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10/800,323

03/11/2004

Jessica G. Chiu

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7590

05/14/2007

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EXAMINER

SHELL, LAURA C

ART UNIT

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3767

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/800,323	Applicant(s) CHIU ET AL.	
	Examiner Laura C. Schell	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

In response to Applicant's traversal of the previous restriction requirement, the examiner has reviewed the application and has come to the conclusion that applicant's traversal was correct. Therefore the examiner has reviewed the application and concluded that a new restriction requirement is necessary, which follows below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, 16-19, 26-53, 58-60 and 69-78 drawn to a catheter for occlusion, infusion and/or perfusion, classified in class 604, subclass 96.01.
- II. Claims 14 and 15, drawn to a method of performing a venogram and then infusion, classified in class 604, subclass 500.
- III. Claims 61-68, drawn to a method of occlusion and then infusion, classified in class 604, subclass 507.
- IV. Claim 20, drawn to a method of making a balloon, classified in class 264, subclass 165.
- V. Claims 21-25, drawn to a filtering device, classified in class 606, subclass 200.

VI. Claims 54-57, drawn to a device to inflate balloons, classified in class 604, subclass 97.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as using the catheter for stopping blood flow to a certain region of the body in order to allow for surgical procedures to be done without the interference of blood flow to that region, or to stop blood flow such that a certain region may be removed from the body and thus excessive bleeding is prevented during the procedure.

Inventions III and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process, such as using the catheter for stopping blood flow to a certain region of the body in order to allow for surgical procedures to be done without the interference of blood flow to that region, or to stop blood flow such that a certain

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region may be removed from the body and thus excessive bleeding is prevented during the procedure.

Inventions IV and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product can be made by another and materially different process such as making the balloon by gluing a cylindrical piece of material to a catheter shaft.

Inventions I and V are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the different inventions of group I and V have different designs, in that group I is an occlusion/infusion/perfusion catheter, while group V is an embolic filtering device. Therefore, groups I and V also have different operations (one is for either occluding a vessel, infusing a treatment agent or permitting perfusion, while five is for catching emboli) and different effects (one leaves a vessel occluded, infused or allows perfusion, while five removes emboli from the bloodstream). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions I and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups I and VI have different designs, in that group I is an occlusion/infusion/perfusion catheter, while group VI is a device used for inflating balloons. Therefore, groups I and VI also have different operations (one is for either occluding a vessel, infusion a treatment agent or permitting perfusion (i.e. the purpose and operation of group I results in a treatment being performed), while six is a device that is used to inflate a balloon (i.e. the operation of group VI results in the production of pressurized fluid) and different effects (one leaves the vessel occluded, infused or allows perfusion, while six produces a pressurized fluid) Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and III are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups II and III have different effects. Group II for example, is a process which performs a venogram for sensing a pressure in a lumen in order to

determine the health of the vessel and then infuses the vessel for any number of reasons (to treat an unhealthy area of the vessel, as determined by the venogram, to remove an obstruction, as determined by the venogram, etc.). Group III, for example, is a process which occludes a vessel and then infuses the vessel, for any number of effects (occluding to prevent blood flow to a certain site so that treatment/infusion can be performed at that site, occluding to prevent the infused fluid from traveling past the occluded site, etc.). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups II and IV have different effects. Group II, for example, is a method of performing a venogram and infusion which results in a treatment. Group IV, for example, is a method of making a balloon, which results in an element of a final product. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and V are directed to related product and process. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect;

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(2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the different inventions of group II and V have different designs, in that group II is a method of using an occlusion/infusion/perfusion catheter for a venogram and then infusion, while group V is an embolic filtering device. Therefore, groups II and V also have different operations (two is for either occluding a vessel, infusing a treatment agent or permitting perfusion, while five is for catching emboli) and different effects (two leaves a vessel occluded, infused or allows perfusion, while five removes emboli from the bloodstream). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions II and VI are directed to related process and product. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups II and VI have different designs, in that group II is a method of using an occlusion/infusion/perfusion catheter for performing a venogram and then infusion, while group VI is a device used for inflating balloons. Therefore, groups II and VI also have different operations (two is for either occluding a vessel, infusion a treatment agent or permitting perfusion (i.e. the purpose and operation of group II results in a treatment being performed), while six is a device that is



used to inflate a balloon (i.e. the operation of group VI results in the production of pressurized fluid) and different effects (two leaves the vessel occluded, infused or allows perfusion, while six produces a pressurized fluid) Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and IV are directed to related processes. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups III and IV have different effects. Group II, for example, is a method of performing occlusion and infusion which results in a treatment. Group IV, for example, is a method of making a balloon, which results in an element of a final product. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and V are directed to related product and process. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed the different inventions of group II and V have different designs, in that group III is a method of performing an occlusion and infusion, while

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group V is an embolic filtering device. Therefore, groups III and V also have different operations (three is for either occluding a vessel, infusing a treatment agent, while five is for catching emboli) and different effects (three leaves a vessel occluded, infused or allows perfusion, while five removes emboli from the bloodstream). Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions III and VI are directed to related process and product. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups III and VI have different designs, in that group III is a method of performing an occlusion/infusion catheter for performing an occlusion and then infusion, while group VI is a device used for inflating balloons. Therefore, groups III and VI also have different operations (three is for either occluding a vessel, infusion a treatment agent or permitting perfusion (i.e. the purpose and operation of group III results in a treatment being performed), while six is a device that is used to inflate a balloon (i.e. the operation of group VI results in the production of pressurized fluid) and different effects (three leaves the vessel occluded, infused or allows perfusion, while six produces a pressurized fluid) Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV and V are directed to related process and product. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups IV and V have different designs. Group IV, for example, is a method of making a balloon and uses different elements and products to produce a finished balloon, while Group V is a filtering device and has a different design as it is a device used only for filtering and does not involve a balloon. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions IV and VI are directed to related process and product. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups IV and VI have different designs. Group IV, for example, is a method of making a balloon and uses different elements, materials and products to produce a finished balloon. Group VI, however, is a device to inflate balloons, and uses different components and elements than the process of producing a balloon. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Inventions V and VI are directed to related products. The related inventions are distinct if the (1) the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect; (2) the inventions do not overlap in scope, i.e., are mutually exclusive; and (3) the inventions as claimed are not obvious variants. See MPEP § 806.05(j). In the instant case, the inventions as claimed in groups V and VI have different designs. Group V, for example is a filtering device which uses different elements and materials to provide the end product of a filtering device than group VI. Group VI is a device used to inflate balloons and has different elements and materials to provide the end product of an inflation device. Furthermore, the inventions as claimed do not encompass overlapping subject matter and there is nothing of record to show them to be obvious variants.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

**If applicant elects group I, please elect one of the species from the group of species pertaining to occlusion/infusion catheter devices below (as applicant's drawings and disclosure disclose numerous different embodiments of these devices).**

**If applicant elects group II, please elect one of the species from the group pertaining to the occlusion/infusion catheter devices below (as the method in group II will inevitably be using one of the numerous different embodiments of the these devices disclosed in the figures and specification).**

**If applicant elects group III, please elect one of the species from the group pertaining to the occlusion/infusion catheter devices below (as the method in group II will inevitably be using one of the numerous different embodiments of the these devices disclosed in the figures and specification).**

**If applicant elects group V, please elect one of the species from the group of species pertaining to filtering devices below (as applicant's drawings and disclosure disclose numerous different embodiments of these devices).**

**If applicant elects group VI, please elect one of the species from the group of species pertaining to inflation devices below (as applicant's drawings and disclosure disclose numerous different embodiments of these devices).**

**The examiner has not found multiple embodiments or species for group IV, therefore no election is necessary if this group is chosen.**

**Occlusion/infusion catheter Species**

Species A: Figs. 3a, 3b, 4

Species B: Figs. 5, 6

Species C: Fig. 20

Species D: Fig. 21

Species E: fig. 22

Species F: fig. 23, 24

Species G: Fig. 25

Species H: Fig. 26-29

Species I: Fig. 30

Species J: Fig. 31

Species K: Fig. 32

Species L: Fig. 35

Species M: Fig. 36

Species N: Fig. 37

Species O: Fig. 38

Species P: Fig. 39

Species Q: Fig. 40

Species R: Fig. 41, 42a, 42b, 42c

Species S: Fig. 43

Species T: Fig. 44

Species U: Fig. 45

Species V: Figs. 48, 51

Species W: Figs. 49a, 49b, 52

Species X: Figs. 50, 53

Species Y: Figs. 64a, 64b, 65a, 65b, 66a, 66b, 67a, 67b

Species Z: Fig. 69a, 69b, 69c, 69d, 69e, 69f, 70

Species AA: Fig. 71a, 71b, 74a, 74b

Species BB: Figs. 72a, 72b

Species CC: Fig. 73

Species DD: Fig. 83-85

Species EE: Figs. 86 and 87

Species FF: Fig. 88

Species GG: Fig. 89

#### **Filtering device species**

Species HH: Fig. 7, 8

Species II: Fig. 9, 10, 17

Species JJ: Fig. 11

Species KK: Fig. 12

Species LL: Fig. 13

Species MM: Fig. 14

Species NN: Fig. 15

Species OO: Fig. 16

Species PP: Fig. 18

**Inflation device species**

Species QQ: Fig. 57

Species RR: Fig. 58

Species SS: Fig. 59

Species TT: Fig. 60

Species UU: Fig. 61

Species VV: Fig. 62

Species WW: Fig. 75a, 75b, 76, 77, 78, 79, 80

Species XX: Fig. 81

The species are independent or distinct because each discloses a different embodiment of either a catheter or filtering device or inflation device, each with patentably distinct features.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claim is generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims



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readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER



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